



## **Drug Utilisation Sub-Committee Outcome Statement 1 October 2015**

The Drug Utilisation Sub-Committee (DUSC) of the Pharmaceutical Benefits Advisory Committee (PBAC) held its 85th meeting on 1 October 2015.

DUSC is a national focus of excellence in collecting, analysing and interpreting data on the utilisation of medicines in Australia for use by the PBAC. Review of the utilisation of medicines is an essential management tool in facilitating the objectives of the National Medicines Policy.

### **Submissions to the PBAC**

DUSC noted that 33 major submissions had been received for the November 2015 meeting of PBAC. DUSC provided detailed advice to the PBAC on projected usage and financial cost for major submissions where there is high cost, uncertain utilisation, first medicine in class or quality use of medicines concerns. The agenda for the November 2015 PBAC meeting can be found on the [PBS website](#).

### **Utilisation of PBS Listed Medicines**

DUSC regularly examines utilisation of PBS items when there is at least 24 months of prescription data available and where DUSC or the PBAC has highlighted items of interest. When an analysis of utilisation is to be undertaken sponsors are notified, provided with a copy of the report and an opportunity to comment prior to the DUSC meeting. All reports, Sponsor comments and DUSC consideration of the reports are subsequently provided to the PBAC.

Full restrictions for PBS listed medicines are available in the [PBS Schedule](#).

DUSC reviewed the utilisation of the following PBS medicines/groups of medicines in October 2015:

#### **Pregabalin for neuropathic pain**

Over 430,000 people were dispensed pregabalin in the second year of availability through the PBS. The number of people treated and the number of prescriptions dispensed has been higher than expected and is continuing to trend upwards. Over 40% of people do not continue pregabalin after the first prescription. The average dose of pregabalin in clinical practice is lower than expected. DUSC considered that these findings raise a number of questions around how pregabalin is being used in practice including whether up-titration of the dose is optimal and whether there is use outside of the subsidy criteria for acute pain or fibromyalgia.

The DUSC requested that the report be provided to the PBAC and to NPS MedicineWise.

#### **Ipilimumab and dabrafenib for metastatic melanoma**

The utilisation of ipilimumab has been lower than expected. This is mainly due to the number of doses per patient and the proportion of patients receiving re-induction therapy being lower than predicted. The number of patients treated with dabrafenib is consistent with that estimated at the time of listing. Based on data available to date the duration on dabrafenib has been shorter than predicted.

DUSC noted that the treatment algorithm and evidence base for melanoma is evolving rapidly and it is important to consider utilisation in this context. DUSC considered that utilisation seems to be moving in accord with best practice guidelines and PBS restrictions.

The DUSC requested that the report be provided to the PBAC.

### **Multiple sclerosis**

DUSC noted that the usage of medicines for relapsing-remitting multiple sclerosis (RRMS) had increased with the availability of oral therapy. DUSC considered that this indicated a greater willingness of patients to receive treatment with oral medicines. Patients appear to persist longer on oral compared to injectable therapy based on a length of treatment analysis of fingolimod.

In its first year of listing the utilisation of dimethyl fumarate has been higher than predicted. DUSC considered that this could relate to the broadening of the McDonald criteria for the diagnosis of multiple sclerosis, concerns over the cardiac side effects for fingolimod and an underestimation of the growth in the RRMS market. The usage of teriflunomide in its first listing year was substantially lower than expected.

The DUSC requested that the report be provided to the PBAC.

### **Nutritional products**

There has been a substantial decrease in the utilisation of amino acid (AA) formulae for cows' milk protein intolerance and allergy following the July 2012 restriction changes. Between 2011 and 2014, the number of patients supplied AA formulae decreased by 31% and has since stabilised. At the same time the number of patients supplied protein hydrolysate (PH) formulae increased 24%. The DUSC considered that the changes to the PBS restrictions effective July 2012 have been successful in their intent and that current PBS use of AA and PH formulae appears to be more in line with clinical guidelines than PBS use prior to the restriction changes. The DUSC considered that the increased use of PH formulae and concurrent decrease in use of AA formulae since the July 2012 restriction changes indicate that more prescribers are following the clinical guidelines which recommend the use of PH formula in infants with cows' milk protein allergy prior to an AA formula, except in infants who have had an anaphylactic reaction to cows' milk protein, where AA formula is the first choice of formula.

There is a large group of children supplied AA formulae who are aged 2 years and older. Almost 900 patients aged 2 years and older are supplied AA formulae each quarter. In 2014, this represented over 25% of patients supplied AA formulae. This is in contrast to PH formulae which have fewer than 300 patients aged 2 years and older supplied each quarter, representing less than 13% of PH patients in 2014. In 2014, this represented 30% and 19% of total expenditure for AA and PH formulae respectively.

The DUSC requested that the report be provided to the PBAC.

### **Biological disease-modifying anti-rheumatic drugs (bDMARDs) for psoriatic arthritis**

The number of patients on bDMARD treatment for psoriatic arthritis has grown substantially since first listing, from about 900 patients in 2007 to nearly 5,000 in 2014. The number of new patients has also increased, from about 570 in 2007 to about 1,000 in 2014 with no indication of stabilising.

Treatment continuation is high with 76-84% of new patients receiving a second authority approval for a bDMARD. DUSC noted that continuation rates in practice are generally higher than expected based on response rates from the key clinical trials. Most patients remain on treatment for long durations. For psoriatic arthritis that follows a relapsing/remitting disease course, the DUSC noted that the current PBS restrictions do not allow patients who have demonstrated a response to have a treatment break and recommence at a later date as part of the same treatment cycle. DUSC considered that this may be contributing to long durations on therapy.

DUSC considered that the understanding of clinical manifestations of psoriatic arthritis has evolved since bDMARDs were first made available through the PBS in 2006. DUSC noted differences between clinical guidelines and PBS restrictions that may impact on use of these medicines in practice. DUSC considered that a review of the restrictions for bDMARDs for psoriatic arthritis may be required.

The DUSC requested that the report be provided to the PBAC.

### **Alprazolam for panic disorder**

The DUSC considered that rescheduling has helped to curb use of alprazolam and that this is evident in both the PBS and non-PBS prescription market. The PBS use of alprazolam declined by about one third immediately after rescheduling from schedule 4 to schedule 8 on 1 February 2014 and has continued to decline since. The DUSC noted this decline was unique to alprazolam and not observed in other benzodiazepines.

Around the time of the rescheduling, approximately double the number of patients switched from alprazolam to diazepam or oxazepam compared to usual levels. The DUSC considered a shift to be expected, but noted there may not be a decline in overall use of benzodiazepines unless further steps are taken to reduce and cease benzodiazepine use. The DUSC was also concerned that there could be a shift to other potentially inappropriate medicines such as antipsychotics.

The DUSC requested that the report be provided to the PBAC. The DUSC requested that the PBAC consider whether any further restriction on the prescribing of alprazolam is required. Such changes could include reducing the maximum quantity and repeats available through the PBS or limiting prescribing to psychiatrists or specially-trained GPs.

## **Upcoming Utilisation Analysis of PBS Listed Medicines**

Utilisation of the following medicines and therapeutic areas have been selected for consideration at future DUSC meetings.

### **Predicted versus Actual Utilisation Analysis**

- Rotigotine for Parkinson's disease
- Ticagrelor for treatment of acute coronary syndrome

### **Analysis of multiple medicines in a treatment area**

- Medicines for smoking cessation
- Biological disease modifying anti-rheumatic drugs (bDMARDs) for the treatment of ankylosing spondylitis
- Medicines for dementia: review of utilisation 24 months after changes to the PBS restrictions arising from the Post-Market Review of PBS anti-dementia drugs. (<http://www.pbs.gov.au/info/reviews/anti-dementia-drugs>)

An outcome statement will be available following each meeting of DUSC. For further information, please contact the DUSC Secretariat at [DUSC@health.gov.au](mailto:DUSC@health.gov.au).

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